

REMARKS

I. Claims Rejection 35 USC § 112

Reconsideration is requested of the rejection of claims 13-15, and 20-21 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While it is maintained that the requirement was not indefinite, claims 13 and 20 have been amended to specify a numerical value. Support for the amendment in the specification, as filed, may be found, for example, at page 12, lines 4-8.

Reconsideration is requested of the rejection of claims 23-26 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 has been amended to omit the term a "binding amount."

Reconsideration is requested of the rejection of claim 23 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "synthetic" has been substituted for "artificial" to improve antecedent basis.

III. Rejection of Claims 1-3, 6, 10 and 63 under 35 USC § 103

Reconsideration is requested of the rejection of claims 1-3, 6, 10 and 63 under 35 USC § 103(a) as being unpatentable over Samid et al., US Patent No. 6,037,376, in view of Rubenstein et al., US Patent Publication No. 2002/0115619, and further in view of Blasé et al., U.S. Patent No. 5,272,137.

As recognized by the Office, Samid et al. do not disclose the use of aspartame and potassium acesulfame, in combination, as sweetening agents. Nor do Rubenstein et al. According to the Office, this combination is disclosed by Blasé et al. in the abstract; column 1, lines 6-10 and 62-68; column 4, lines 29-34 and 55; and line 6 and column 5. The Office,

however, is mistaken. No such disclosure appears in the Blasé et al. patent. For the Office's convenience, these passages are reproduced below.

"The present invention relates to an aqueous pharmaceutical suspension composition comprising: from about 0.2% to 20% of a substantially water soluble pharmaceutical active, e.g. acetaminophen; a suspension stabilizing effective amount of xanthan gum and microcrystalline cellulose; an effective amount of taste masking compositions; and water, as well as a process for producing such aqueous pharmaceutical suspensions."¹

"In one aspect, this invention relates to a pharmaceutical suspension composed of pharmaceutical actives, suspension agents, sweetening agents and flavoring agents."²

"In view of these difficulties it would be desirable to develop a ready-to-use pharmaceutical suspension with a high degree of stability and good taste masking characteristics. Therefore, there exists a need for a suspension system for pharmaceutical actives that minimizes sedimentation of the active ingredients and provides a pleasant tasting liquid dosage."³

"The inventive suspension can effectively mask the bitter taste of pharmaceuticals contained in the suspension. Masking the flavor of bitter pharmaceuticals may be accomplished by using flavoring agents and sweeteners to overpower the bitter flavor of the pharmaceutical."⁴

"Examples of suitable artificial sweeteners include but are not limited to aspartame, sucralose, cyclamates, saccharin and mixtures thereof."⁵

Aspartame is listed as a possible sweetener in Blasé, but potassium acesulfame is not. Accordingly, the Office has failed to establish a *prima facie* case of obviousness and the Office's assertion that it would have been obvious to a person of ordinary skill in the art at the time of the invention to employ aromatic flavoring agents, and specific sweetening agents aspartame and potassium acesulfame in the compositions comprising 4-phenylbutyrate taught by Samid et al. and Blasé et al. is simply unsupported.

¹ Abstract

² Column 1, lines 6-10

³ Column 1, lines 62-68

⁴ Column 4, lines 29-34

⁵ Column 4, line 55.

IV. Rejection of Claims 1-3, 6-15, 18-26, 29-32 and 63 under 35 USC §103

Reconsideration is requested of the rejection of claims 1-3, 6-15, 18-26, 29-32, and 63 under 35 USC § 103(a) as being unpatentable over Rubenstein et al., U.S. Patent Publication No. 2002/0115619), in view of Blasé et al., US Patent No. 5,272,137.

As noted above, neither Rubenstein et al. nor Blasé et al. disclose the use of aspartame and potassium acesulfame, in combination, as sweetening agents. Accordingly, the Office has failed to establish a *prima facie* case of obviousness and the Office's assertion that it would have been obvious to a person of ordinary skill in the art at the time of the invention to employ aromatic flavoring agents, and specific sweetening agents aspartame and potassium acesulfame in the compositions comprising 4-phenylbutyrate taught by Rubenstein et al. and Blasé et al.

V. Teleconference with the Examiner regarding Blasé and the rejected claims

In a telephone call on January 17, 2008, Kofi Adzamli contacted the Examiner to discuss the matters raised herein and the Examiner suggested that the error be pointed out in a response. No agreement was reached.

CONCLUSION

In view of the foregoing, applicant respectfully requests all pending rejections be withdrawn and all pending claims be allowed.

Applicant believes no fees are due regarding this response to the Office Action. If this is in error, the Commissioner is hereby authorized to charge any underpayment of Government fees necessitated by this response to Deposit Account No. 19-1345.

Respectfully submitted,



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